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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/305,738	05/06/1999	KLAUS MOSBACH	003300-357	2570

7590 10/19/2004
MORGAN & FINNEGAN LLP
345 PARK AVENUE
NEW YORK, NY 10154

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/305,738	MULLER ET AL.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on July 20 and 27, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-34,36-38 and 46-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-34,36-38 and 46-90 is/are rejected.
- 7) ☒ Claim(s) 87 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1641

1) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submissions filed on July 20 and 27, 2004 have been entered.

2) Claims 27-34, 36-38 and 46-90 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the corresponding claims of U.S. Patent No. 5,959,050 for the reasons of record. Applicants' offer to file a terminal disclaimer upon the indication of allowable subject matter in this application is noted.

3) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

6) Claims 54, 56, 58-71 and 79-86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1641

There is no written description in the specification of the following terms:

- a)** Claim 54: "metal";
- b)** Claim 56: "electrochemiluminescent compound";
- c)** Claim 58: "therapy";
- d)** Claim 68: "assembling a plurality...around a cancer cell";
- e)** Claim 71: "diagnosis";
- f)** Claim 79: "opiate";
- g)** Claim 80: "analyzing a fluid sample";
- h)** Claim 85: "method of purification";

7) Claims 34, 37, 38, 46-71 and 80-86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 34 is indefinite and incomplete in defining "a method for assaying a drug molecule" as comprising only two steps, i.e. "providing" a sample and "contacting" the sample with the antibody; these two steps do not constitute an assay method. There is no recitation of any step which requires binding of the sample to the antibody, nor are there steps which require the detection of such binding and the correlation of the detection with the amount/presence of drug in the sample. See also, all claims dependent on claim 34.

b) For claim 53 which is dependent from claim 34, it is unclear why, if a "drug molecule in a fluid" (presumably a drug in a biological fluid) is being assayed, the drug molecule would comprise a "label". It is also unclear how the "label" would be involved in the assay of claim 34 which requires only the steps described in **a)** above.

c) Product claim 57 is improperly dependent from method of use claim 34.

d) It is unclear what is meant by the word "therapy" in claim 58 since both the type of therapeutic effect and the type of "imprinted molecule" are unspecified.

Art Unit: 1641

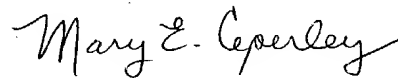
- e)** For claim 60, it is unclear how the step of "providing" and additional antibody ("further comprising") affects or is related to the "method of therapy" described in claim 58.
- f)** It is unclear what is meant by the term "holding" in claim 61. See also, claim 69.
- g)** In claims 62 and 63, it is unclear what is meant by the term "encountering".
- h)** Claims 66 and 67 do not make sense for the reason that the additional method step recites an effect.
- i)** For claim 69, the "providing" step is redundant with the first step of independent claim 58; the single "step" appears to inconsistently include two steps, i.e. "providing" and "transporting".
- j)** For claim 71, a "method of diagnosis" would not result from the "providing" and "administering" an antibody.
- k)** For claims 80-84, the steps of "providing" an antibody and "administering said artificial antibody to a fluid sample" do not constitute "a method of analyzing a fluid sample".
- l)** For claims 85 and 86, it is unclear what the body is "purified" from. There is no requirement for any binding of the antibody to its corresponding antigen, nor is there any requirement that the antigen/antibody complex be removed from the blood.
- 8)** Claim 87 is objected to as being a duplicate of claim 27. "Biocompatible" would be an inherent feature of and would not further limit the antibody of "particle size of less than about five microns".
- 9)** Claims 27-33, 36, 72-78 and 88-90 are drawn to allowable subject matter.
- 10)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 15, 2004



Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641